

REMARKS

Applicants acknowledge receipt of the Office Action mailed July 28, 2009.

In the Office Action¹, the Examiner objected to the drawings; rejected claims 10-13, 15, 17, and 19-23 under 35 U.S.C. § 112, first paragraph; rejected claims 10-13, 15, 17, and 19-23 under 35 U.S.C. § 112, second paragraph; rejected claims 1, 3, 7, and 9 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* (U.S. Patent No. 5,730,753) in view of *Abulhaj et al.* ("*Abulhaj*") (U.S. Patent No. 6,852,119); rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Abulhaj*, and further in view of *Duchon et al.* ("*Duchon*") (U.S. Patent No. 5,964,718); rejected claims 10-12 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert et al.* ("*Hofert*") (U.S. Patent No. 4,203,446); rejected claims 13, 15, 19, and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Abulhaj*; and rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita* and *Abulhaj*, and further in view of *Duchon*.

Claim 5 was not rejected. Applicants assume that since the Examiner has failed to provide grounds for rejection for dependent claim 5, dependent claim 5 contains allowable subject matter. Applicants further submit that the cited prior art references fail to teach or suggest the limitation of dependent claim 5.

By this Amendment, Applicants amend claims 1, 10, and 13, and add new claims 38 and 39. Upon entry of this Amendment, claims 1, 3, 5, 7-13, 15, 17, and 19-39 will

¹ The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

be pending, with claims 24-37 withdrawn from consideration. Of the claims under examination, claims 1, 10, and 13 are independent.

The originally-filed specification, claims, abstract, and drawings fully support the amendments to claims 1, 10, and 13, and the addition of new claims 38 and 39. No new matter has been introduced.

Based on the foregoing amendments and the arguments that follow, Applicants traverse the rejections above and respectfully request reconsideration for at least the reasons that follow.

I. OBJECTIONS TO THE DRAWINGS

The drawings stand objected to under 37 C.F.R. § 1.83(a) because the drawings must show every feature of the invention specified in the claims. *See* Office Action, p. 2. Specifically, the Examiner alleges, “the limitation found in claim[s] 10 and 13 that the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring must be shown or the feature(s) canceled from the claim(s).” *Id.* Applicants respectfully disagree. Applicants submit that the limitation cited above is illustrated in Applicants’ FIGs. 4 and 5, as discussed and depicted below in Section II, pages 16 and 17, of this reply. Applicants therefore request that the objection to the drawings be withdrawn.

II. 35 U.S.C. § 112, FIRST PARAGRAPH, REJECTIONS

Claims 10-13, 15, 17, and 19-23 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

First, the Examiner alleges, "[c]laims 10 and 13 recite 'the one or more spring surfaces of the lancet holder engages both the internal compression spring and the external compression spring.' This statement has no support in the original disclosure." (*Office Action*, p. 3, ll. 15-17). Applicants respectfully disagree.

The lancet holder 34, which extends from the barrel holder 39 on the proximal end to the retaining features 36 on the distal end, includes a spring surface 41 along the top and bottom surfaces thereof. Near the distal end of the lancet holder 34, the spring surface 41 extends past the slot 33 of the interior tube 26 to the tip of the retaining features 36. As disclosed on page 9, lines 5-7 of Applicants' specification, "[t]he lancet holder 34 . . . comprise[s] one or more internal spring surfaces 41 against which the internal spring 32 can act to propel the lancet 20." Further, as illustrated in Applicants' FIG. 4 below, the internal compression spring 32 engages the spring surface 41 of the lancet holder 34 within the interior tube 26. Similarly, the external compression spring 44 also engages a portion of the spring surface 41 which extends past the slot 33 of the interior tube 26, near the tip of the retaining features 36 (FIG. 5 below). Accordingly, the spring surface 41, along the top and bottom surfaces of the lancet holder 34, engages both the internal compression spring 32 and the external compression spring 44.

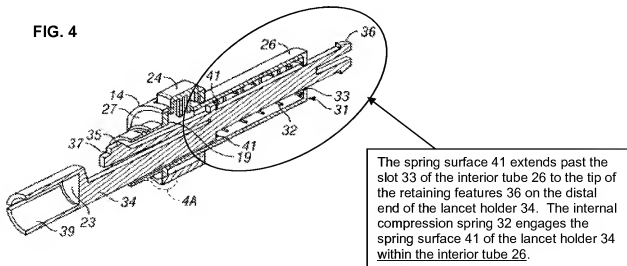
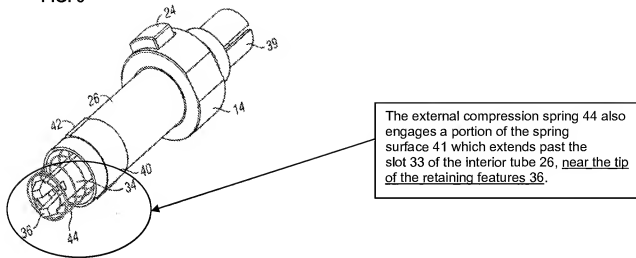


FIG. 5



Second, the Examiner asserts, "[c]laims 15 and 17 recite[] 'the detent forms a slotted portion of the collar ramp.' The combination of a cantilevered detent and a slotted portion are not disclosed in the original disclosure as being in the same embodiment. The original disclosure states that in a first embodiment the detent forms a cantilevered portion and in a second embodiment the detent forms a slotted portion; therefore the combination of this two is considered new matter." (*Office Action*, p. 4, para. 4). Although Applicants do not necessarily agree with the Examiner's assertion, Applicants have amended claims 1 and 13 and added new claims 38 and 39 in an effort to expedite prosecution. Applicants therefore submit that the rejection of claims 10-13, 15, 17, and 19-23 under 35 U.S.C. § 112, first paragraph, has been rendered moot, and request that the rejection be withdrawn.

III. 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTIONS

Claims 10-13, 15, 17, and 19-23 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

First, the Examiner asserts that “[c]laim[s] 10 and 13 state ‘one or more spring surfaces at the distal end and one or more lancet holding features at the proximal end.’ It is unclear to the examiner if the distal and proximal end are with respect to which claim component.” (*Office Action*, p. 4, para. 7). Applicants respectfully submit that claims 10 and 13 clearly recite that the lancet holder comprises a distal end and a proximal end, with the retaining features 36 and the spring surfaces 41 being at the distal end of the lancet holder 34, and the lancet holding features 23 and 39 being at the proximal end of the lancet holder 34.

Second, the Examiner alleges that there is insufficient antecedent basis for the following limitations in claims 10 and 13: “the distal end,” “the proximal end,” and “the distal end of the interior tube.” (*Office Action*, p. 8, paras. 8 and 9). In response, Applicants have amended claims 10 and 13.

Applicants submit that the rejections of claims 10-13, 15, 17, and 19-23 have been rendered moot by the amendments to claims 10 and 13. Applicants therefore request that the rejection of claims 10-13, 15, 17, and 19-23 under 35 U.S.C. § 112, second paragraph, be withdrawn.

IV. 35 U.S.C. § 103 REJECTIONS

Applicants traverse the rejection of claims 1, 3, 7, and 9 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Abulhaj*. Applicants respectfully disagree with the Examiner’s arguments and conclusions and submit that independent claim 1 patentably distinguishes over *Morita* and *Abulhaj* at least for the reasons described below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See id. “A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention.” M.P.E.P. § 2145. Furthermore, “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art” at the time the invention was made. M.P.E.P. § 2143.01(III), internal citation omitted. Moreover, “[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.” M.P.E.P. § 2141.02(I), internal citations omitted (emphasis in original).

“[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art.” M.P.E.P. § 2141(II). “Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.” M.P.E.P. § 2141(III).

Independent claim 1 recites an adjustable nozzle assembly comprising: “a collar comprising a collar pin that engages the ramped groove and slides relative to the

ramped groove, the collar being adapted to rotate relative to the interior nozzle; . . . wherein the collar comprises a sloped collar ramp with a cantilevered detent on one end, wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation.”

Morita appears to disclose an assembly for adjusting a pricking depth of a lancet including a cap element 3, an adjusting element 5, and a cover element 7. The cap element 3 includes a thread portion 17, and the adjusting element 5 includes a thread portion 53. The thread portion 53 is constructed such that it is engaged with a thread groove 47 of the thread portion 17 through a screw engagement mechanism. (*Morita*, col. 11, ll. 1-28 and col. 12, ll. 60-67).

As admitted by the Examiner, “*Morita* discloses the claimed invention except for the location of the notches and the detents.” (*Office Action*, p. 6, ll. 18-19). The Examiner further admits “*Morita* does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends.” (*Id.* at p. 7, ll. 3-5). Additionally, the Examiner submits that “*Morita* in view of *Abulhaj* discloses the claimed invention except for the slope of the collar ramp and the slope of the mating ramp being approximately equal.” (*Id.* at p. 8, ll. 13-14). *Morita* also fails to disclose “wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation,” as recited in independent claim 1 (emphasis added).

The Examiner alleges that “*Morita* . . . discloses . . . a plurality of adjustment notches (39) . . . ; [and] a collar (5) [which] comprises a sloped collar ramp (the ramp in

portion 51) with a cantilevered detent (51 which is part of 23 which is cantilevered) on one end (Fig. 2), wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation.” (*Office Action*, p. 6, ll. 11-17). Applicants respectfully disagree. The protruding portion 51, which the Examiner equates to the claimed “detent,” does not engage and disengage the recess portions 39, which the Examiner equates to the claimed “adjustment notches.” Rather, as disclosed in *Morita* in column 12, lines 52-59, “[a]t least one of the peripheral flap portion 21 comprises the tab portion 23 which has the protruding portion 51 on its inside end. The protruding portion 51 falls into the recess portion 41 of the cap element . . . , whereby the peripheral screw-like rotation of the protruding portion 51 of the adjusting element 5 is allowed within the recess portion 41 while undue removal of the adjusting element 5 from the cap element 3 is prevented” (emphasis added). Accordingly, the protruding portion 51 engages with the recess portion 41, not the recess portions 39.

In order to cure the deficiencies of *Morita*, the Examiner relies on *Abulhaj* and alleges “*Abulhaj* discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism[,] . . . where the groove has an assembly groove . . . extending in a first direction . . . and a ramped groove . . . extending in a second direction.” (*Office Action*, p. 7, ll. 6-11). Such teaching, even if present in *Abulhaj*, however, does not constitute or suggest at least an adjustable nozzle assembly “wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation,” as recited in independent claim 1.

As explained above, the elements of independent claim 1 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither determined the scope and content of the prior art nor ascertained the differences between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 1. Claim 1, and claims 3, 7, and 9 which depend therefrom, are patentable over *Morita* and *Abulhaj*. Applicants therefore request that the rejection of claims 1, 3, 7, and 9 under 35 U.S.C. § 103(a) be withdrawn.

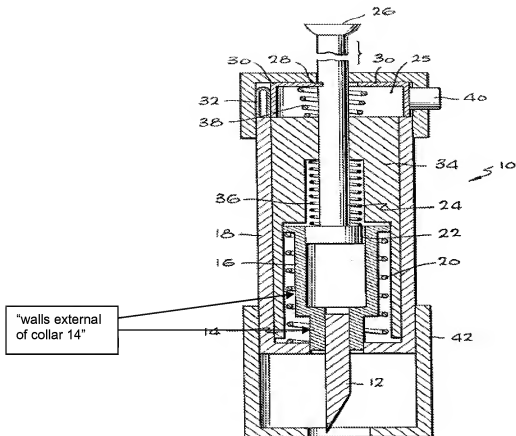
Applicants traverse the rejection of claims 10-12 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that independent claim 10 patentably distinguishes over *Hofert* at least for the reasons described below.

Independent claim 10 recites a rearward body assembly of a lancing device comprising: "a lancet holder comprising one or more retaining features . . . at a distal end . . . ; an interior tube comprising an open end and a slotted end through which the one or more retaining features extend . . . ; . . . a retainer comprising a slotted surface at a distal end of the interior tube through which the one or more retaining features extend; . . . and an external compression spring comprising a first end and a second end, the first end comprising a reduced coil diameter that engages the one or more retaining features of the lancet holder."

Hofert appears to disclose a spring lancet holder for creating accurate standardized, reproducible puncture wounds in the skin for medical diagnostic purposes. (*Hofert*, Abstract). The spring lancet holder 10 includes a lancet 12 mounted within a collar 14, which is formed at one end of a blade guide 16, which is mounted for motion within a housing 18. The blade guide 16 may be moved vertically downward. Retarding this downward motion is a restoring spring 20. (*Id.* at col. 2, ll. 49-58).

As admitted by the Examiner, *Hofert*, however, fails to teach or suggest at least “the rearward body is positioned around the periphery of the interior tube.” (*Office Action*, p. 12, ll. 1-2). *Hofert* also fails to disclose “a lancet holder comprising one or more retaining features . . . at a distal end . . . ; [and] . . . a retainer comprising a slotted surface at a distal end of the interior tube through which the one or more retaining features extend.”

The Examiner alleges that *Hofert* discloses “a lancet holder (16) comprising one or more retaining features (retaining features are the walls external of part 14 which compress the lancet in place).” (*Office Action*, p. 9, line 22 - p. 10, line 2). Applicants respectfully disagree.



With respect to the “walls external of part 14,” identified in the figure from *Hofert* above, which the Examiner equates to the claimed “one or more retaining features,” do not and structurally cannot extend through the collar 14 itself, which the Examiner equates to the claimed “retainer.” Since the external walls of the collar 14 form a perimeter and enclosing structure around the collar 14, it is impossible for the external walls to actually extend through the collar 14.

As explained above, the elements of independent claim 10 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither determined the scope and content of the prior art nor ascertained the differences

between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 10. Claim 10, and claims 11 and 12 which depend therefrom, are patentable over *Hofert*. Applicants therefore request that the rejection of claims 10-12 under 35 U.S.C. § 103(a) be withdrawn.

Applicants traverse the rejection of claims 13, 15, 19, and 21-23 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita*, and further in view of *Abulhaj*. Applicants respectfully disagree with the Examiner's arguments and conclusions and submit that independent claim 13 patentably distinguishes over *Hofert*, *Morita*, and *Abulhaj* at least for the reasons described below.

Independent claim 13 recites a lancing device comprising: "(i) an adjustable nozzle assembly through which the lancet can be propelled into a lancing surface, the adjustable nozzle assembly comprising: . . . a collar comprising a collar pin that engages the ramped groove and slides relative to the ramped groove, the collar being adapted to rotate relative to the interior nozzle; . . . wherein the collar comprises a sloped collar ramp with a cantilevered detent on one end, wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation; . . . and (ii) a rearward body assembly, the rearward body assembly comprising: a lancet holder comprising one or more retaining features . . . at a distal end . . . ; an interior tube comprising an open end and a slotted end through which the one or more retaining

features extend . . . ; . . . a retainer comprising a slotted surface at a distal end of the interior tube through which the one or more retaining features extend; . . . and an external compression spring comprising a first end and a second end, the first end comprising a reduced coil diameter that engages the one or more retaining features of the lancet holder.”

As discussed above, *Hofert* appears to disclose a spring lancet holder for creating accurate standardized, reproducible puncture wounds in the skin for medical diagnostic purposes. (*Hofert*, Abstract). The spring lancet holder 10 includes a lancet 12 mounted within a collar 14, which is formed at one end of a blade guide 16, which is mounted for motion within a housing 18. The blade guide 16 may be moved vertically downward. Retarding this downward motion is a restoring spring 20. (*Id.* at col. 2, ll. 49-58).

Further as discussed above, *Morita* appears to disclose an assembly for adjusting a pricking depth of a lancet including a cap element 3, an adjusting element 5, and a cover element 7. The cap element 3 includes a thread portion 17, and the adjusting element 5 includes a thread portion 53. The thread portion 53 is constructed such that it is engaged with a thread groove 47 of the thread portion 17 through a screw engagement mechanism. (*Morita*, col. 11, ll. 1-28 and col. 12, ll. 60-67).

As admitted by the Examiner, *Hofert*, however, “does not disclose an adjustable nozzle assembly.” (*Office Action*, p. 13, line 14). The Examiner further submits, “*Hofert* in view of *Morita* does not disclose that the ramped groove is extending in a second direction deviating from the first direction in which the assembly groove extends.” (*Id.* at p. 14, ll. 1-4).

Accordingly, in order to cure the deficiencies of *Hofert* and *Morita*, the Examiner relies on *Abulhaj* and alleges “*Abulhaj* discloses a lancet with an adjustable depth mechanism in which a cap (18) is adjustable by a pin/groove mechanism[.] . . . where the groove has an assembly groove . . . extending in a first direction . . . and a ramped groove . . . extending in a second direction.” (*Office Action*, p. 14, ll. 5-11). Such teaching, even if present in *Abulhaj*, however, does not constitute or suggest at least a lancing device “wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation” (emphasis added). *Abulhaj* also fails to teach or suggest “a lancet holder comprising one or more retaining features . . . at a distal end . . . ; [and] . . . a retainer comprising a slotted surface at a distal end of the interior tube through which the one or more retaining features extend” (emphases added).

As explained above, the elements of independent claim 13 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither determined the scope and content of the prior art nor ascertained the differences between the prior art and the claim. Accordingly, no reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 13. Claim 13, and claims 15, 19, and 21-23 which depend therefrom, are patentable over *Hofert*, *Morita*, and *Abulhaj*. Applicants therefore request that the rejection of claims 13, 15, 19, and 21-23 under 35 U.S.C. § 103(a) be withdrawn.

Applicants traverse the rejection of claim 8 under 35 U.S.C. § 103(a) as being unpatentable over *Morita* in view of *Abulhaj*, and further in view of *Duchon*; and the rejection of claim 20 under 35 U.S.C. § 103(a) as being unpatentable over *Hofert* in view of *Morita* and *Abulhaj*, and further in view of *Duchon*. The deficiencies of *Morita*, *Abulhaj*, and *Hofert* are discussed above.

With respect to *Duchon*, the Examiner alleges “Duchon discloses that the contact surface (48) is concave.” (*Office Action*, p. 9, line 12). Such teaching, even if present in *Duchon*, however, does not constitute or suggest at least an adjustable nozzle assembly “wherein the sloped collar ramp and the detent rotate along the interior nozzle mating ramp causing the detent to engage and disengage the adjustment notches during the rotation, as recited in independent claims 1 and 13, and “a lancet holder comprising one or more retaining features . . . at a distal end . . . ; . . . a retainer comprising a slotted surface at a distal end of the interior tube through which the one or more retaining features extend,” as recited in independent claim 13.

Claims 8 and 20 correspondingly depend from independent claims 1 and 13 and require all elements thereof. As explained above, the elements of independent claims 1 and 13 are neither taught nor suggested by the cited references. Consequently, the Office Action has neither determined the scope and content of the prior art nor ascertained the differences between the prior art and the claims. Accordingly, no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art and a *prima facie* case of obviousness has not been established for claims 8 and 20 at least due to their dependence. Therefore,

Applicants request that the rejection of claims 8 and 20 under 35 U.S.C. § 103(a) be withdrawn.

V. NEW CLAIMS

New claims 38 and 39 correspondingly depend from independent claims 1 and 13 and are allowable at least for the same reasons claims 1 and 13 are allowable. In addition, each of the dependent claims recites unique combinations that are neither taught nor suggested by the cited art, and therefore each also is separately patentable.

VI. CONCLUSION

Applicants respectfully submit that claims 1, 3, 5, 7-13, 15, 17, and 19-23 are in condition for allowance.

In view of the foregoing amendments and remarks, Applicants respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 06-0916.

Respectfully submitted,

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/Eric P. Raciti/

Dated: October 28, 2009

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